GUIDELINES TO BE USED BETWEEN HCFA AND STATE INSURANCE DEPARTMENTS FOR THE MEDICARE+CHOICE PROGRAM

(INCLUDING FEDERALLY WAIVED PSOs)

SCOPE

The purpose of this memorandum is to provide guidance to the states with respect to the authority and responsibility of the Health Care Financing Administration (HCFA) and state insurance regulators regarding the licensure and regulation of Medicare+Choice (M+C) organizations including federally waived Provider Sponsored Organizations (FWPSOs), and to provide for mutual sharing of information between HCFA and states to facilitate each party's role. The guidelines are general and therefore not specific to an individual state. Each state should review its statutes and regulations to determine its role in the regulation of M+C organizations.

This document is not intended to be a binding agreement between HCFA and any state, nor is it a complete discussion of every issue that may arise in connection with the M+C program. Because of the variation in state requirements, it will be necessary for HCFA to evaluate individual issues specific to state law and regulation on a case-by-case basis. While they are not binding, these guidelines, with NAIC concurrence, will assist states in determining their regulatory role and their interaction with HCFA. HCFA will use these guidelines in developing operational policy in the issue areas covered. They will also serve to educate both HCFA and the states and facilitate further dialogue regarding their respective roles in the regulation of M+C organizations.

BACKGROUND

Except for FWPSOs, HCFA and the states are jointly charged with the oversight of M+C organizations. States are charged with the responsibility to license and regulate M+C organizations as risk-bearing entities. HCFA is responsible for ensuring that all M+C organizations meet M+C standards. In addition, even though there can be a waiver of the state licensure requirement and state regulation of FWPSOs, state insurance departments may play a significant role in HCFA's waiver approval process and, upon the granting of the waiver, in enforcing certain FWPSO requirements.

This memorandum clarifies the respective authority and responsibility of HCFA and state insurance regulators regarding the licensure and regulation of both state licensed Medicare+Choice organizations and FWPSOs in the context of the applicable federal laws. The following issue areas are addressed for the two different types of organizations.

State Licensed M+C Organizations:

- M+C State Licensure Requirement
- Federal Preemption of State Licensed M+C Organizations
- Financial Reporting by State Licensed M+C Organizations

Federally Waived PSOs:

- Guidelines for the Waiver Request and Approval Process
- FWPSO Financial Reporting
- FWPSO Compliance with State Consumer Protection and Quality Standards

(For a listing of HCFA staff responsible for each issue area see Attachment A).

REGULATION OF STATE LICENSED M+C ORGANIZATIONS

M+C STATE LICENSURE REQUIREMENT

Background

Except for FWPSOs, Federal regulations at 42 CFR 422.400 require each M+C organization to be licensed under state law, or otherwise authorized to operate under state law, as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each state in which it offers one or more M+C plans. The intent of this requirement is to ensure that each organization offering an M+C plan has the necessary state authority to do so, and it ensures that each organization will meet state solvency standards.

Each M+C organization must have two basic types of state authority. First, each M+C organization must be authorized by the appropriate state regulatory agencies to operate as a risk-bearing entity offering health insurance or health benefits coverage. Examples of this authority include any of the health insurance licenses including indemnity insurance, HMO or PSO. A certificate of authority or some other type of certification to operate as a risk-bearing entity offering health insurance or health benefits may also be acceptable, if this is all the appropriate state regulatory agencies require.

Second, the M+C state licensure requirement also requires that the authority to offer the type of M+C plan the organization wishes to offer (e.g. coordinated care plan, PPO, private fee-for- service, or MSA) be within the scope of its authority to operate as a risk-bearing entity. For example, an organization that is state licensed as an indemnity insurer may not have the necessary state authority to offer an M+C coordinated care plan because operating a health care network is not within the scope of an indemnity license. In this case, the state may require the organization to obtain an HMO license before offering an M+C coordinated care plan. Similarly, a state may require an organization that is a licensed HMO to obtain separate licensure as an indemnity insurer in order to offer an M+C point-of-service (POS) plan. Many state insurance and/or health departments grant this authority through their product approval or material modification processes. Some organizations may have a limited licensure or certification status allowing them to function as risk-bearing entities in certain markets (e.g., Medicaid) or for certain services only (e.g., a prepaid dental plan). For such organizations, the state licensing authority or authorities responsible for licensing comprehensive prepaid plans in the commercial marketplace, or for other Medicare risk plans, would be the appropriate authority for determining whether the offering of a M+C plan is within the scope of the organization's existing license or authority to operate.

M+C State Certification Form

To establish the licensure status of organizations, and in particular to determine compliance with the scope of licensure requirement, HCFA will require, as part of the M+C application process, certification from the appropriate state regulatory agency that both the licensure and scope of licensure requirements are met. The M+C State Certification Form (Attachment B) will be included in the M+C application for this purpose. By signing this form, the appropriate state regulatory agencies will be certifying that the organization has the necessary state authority to operate as a risk-bearing entity offering health insurance or health benefits coverage and to offer the M+C plan or plans it intends to offer.

HCFA will also require organizations licensed to undertake non-commercial business (e.g. Medicaid) to obtain an additional certification from the appropriate state regulatory agency that they meet appropriate solvency standards. M+C applicants that are not licensed for commercial business will also use the M+C State Certification Form to obtain this solvency certification.

FEDERAL PREEMPTION OF STATE LICENSED M+C ORGANIZATIONS

Background

Because M+C organizations must first be state licensed or certified, the states play a key role in the M+C program. However, not all state laws governing health plans and insurers apply to the Medicare+Choice products of a health plan or insurer.

Specific Preemption

Federal law preempts state law in three specific areas:

- 1. Benefits
- 2. Inclusion and treatment of providers; and
- 3. Coverage determinations (including related appeals and grievances).

For example, it is HCFA's position that a state may not require that an organization offer a particular state-mandated benefit to Medicare beneficiaries under a M+C contract, because of the specific preemption of state law in Federal law for M+C benefit determination. Thus, with regard to M+C organizations, states need to determine the provisions of state law that do not apply, or no longer apply, to the M+C products of organizations doing business in the state. (This specific preemption does not apply to non-M+C lines of business, including benefits provided to Medicare enrollees under arrangements that fall outside the scope of the M+C contract—specifically, those benefits, for example, offered only to Medicare beneficiaries connected with a particular employer group or union through a separate arrangement between the M+C offeror and the employer or union.)

General Preemption

Generally, except in the three areas of specific preemption, Medicare+Choice organizations must comply with all state laws and standards applicable to insurers or health plans, as well as all Federal laws and standards applicable to Medicare+Choice organizations and plans. However, as was the case prior to the Balanced Budget Act (BBA), insurers and health plans are not required to adhere to state laws and standards, with respect to their Medicare operations, if those laws or standards are inconsistent with Federal laws and standards. It has been HCFA's policy to consider a state law or standard inconsistent with Federal law only if adherence to the state law or standards prevents the health plan or insurer from complying with a Federal standard. State laws or standards that are more stringent than Federal standards are not, on their face, inconsistent with Federal standards and will rarely be preempted by Federal law, as the BBA makes clear. For example, if there is a state law on prompt payment of claims and payment of interest in the event of late payment which requires interest of 15 percent to be paid on claims reimbursed later than 15 days after the date of service, it would not be preempted by the Federal prompt payment provision requiring payment within 30 days and payment of interest at a variable rate determined by the U.S. Treasury. Again, general preemption applies only to M+C lines of business

Examples of Preemption and Lack of Preemption

For both the specific and general preemption areas, it is not always clear whether Federal preemption applies. Following are examples which might be useful in attempting to clarify Federal preemption:

Clarification of the Three Areas of Specific Preemption. Consistent with HCFA's view that the specific preemptions should be applied as narrowly as possible—that is, HCFA believes it is the intent of the BBA that state statutes and rules prevail in the absence of a specific preemption or when there is an inconsistency between state statutes and Federal rules as described above—the specific preemption for "coverage determinations (including

related appeals and grievances)" is interpreted to apply only to issues that are subject to the Medicare appeals process. HCFA classifies a request for a review of a coverage determination, or request for payment of a claim for what the enrollee believes to be a covered service, as an appeal. HCFA classifies a complaint relating to issues such as difficulty in scheduling an appointment or in length of waiting room time as a grievance (For more information about the M+C appeals and grievances processes see Attachment C). A Medicare beneficiary may file a "grievance" asking for payment of a claim for services received from an out-of-plan provider, but this type of grievance would be classified by HCFA as an appeal that is exclusively subject to the Medicare appeals process.

The Medicare appeals process is the exclusive avenue for settlement of a dispute over whether an item or service is covered under the Medicare+Choice contract (including as a supplemental service or additional benefit not covered under traditional Medicare), but only with respect to the "coverage" issue (whether there is coverage and what the beneficiary liability is for a covered service). The Medicare appeals process is not the exclusive process for all matters that may be *related* to the issue under dispute. HCFA specifies that state tort and contract law may still apply to such disputes. While review of coverage determination must go through the HCFA appeals process, a beneficiary may also have a valid claim under state tort or contract law. Thus, states are allowed to investigate consumer complaints to determine if the complaint falls outside of the specific preemption area, and is therefore subject to state jurisdiction. In order to protect beneficiary rights, states must inform the complainant of his/her Medicare appeal rights (see Attachment C) upon receipt of the complaint. For example, there can be recourse under state law for a claim of malpractice for having delayed the provision of a service that was determined, through the Medicare appeals process, to be covered under the contract. Or there can be a claim under contract law based on language in a member contract justifying reimbursement for services, which were found not to be covered services under the Medicare+Choice contract between the Federal Government and the M+C organization.

Similarly, HCFA has adopted a narrow interpretation of the benefit preemption in the Medicare+Choice interim final regulations. HCFA has limited the benefit preemption to benefits (items and services) *per se* but has not extended the preemption to cost-sharing standards imposed by a state with respect to benefits, even though the state cost-sharing standard may apply to a benefit that is itself preempted. For example, a state may mandate that all Medicare health plans include coverage of prescription drugs with limited copayments. The narrow interpretation of the benefits preemption would say that plans are no longer required to provide any drug benefit (other than what Medicare covers), but to the extent that a plan does cover additional drugs, the state cost-sharing rules will apply.

Practical Applications

In order to more fully illustrate what, if any, preemption rule applies, HCFA, with input from the NAIC, has developed the following tables illustrating specific examples of preemption and absence of Federal preemption:

SPECIFICALLY PREEMPTED

State standards on:

- Direct access to provider requirements, whether in-plan or out-of-plan
- Benefit mandates, other than cost sharing
- Appeals and grievances with respect to coverage determinations
- Inclusion of providers (such as "any willing provider" laws; requirement of inclusion of specific types of providers as network providers).

With regard to the "general preemption," the relationship between Federal standards and state standards remains the same as it was before the passage of the BBA. That is, state standards are preempted only when they conflict with Federal standards. Plans otherwise must meet both Federal and state standards. Examples of state functions and standards that remain unaffected by the specific preemptions of the BBA are listed below.

STANDARDS AND PROCEDURES SUBJECT TO GENERAL PREEMPTION ONLY

IF THERE IS A CONFLICT BETWEEN FEDERAL AND STATE STANDARDS

- Market conduct examinations
- Timely payment of claims standards
- Enforcement actions
- Unfair claim settlement standards governing the process for determination of benefits as opposed to the benefits themselves
- Investigation of consumer complaints
- Filing and review of advertising and marketing materials
- UR programs and standards
- QA programs
- Adequacy of provider network
- Filing and review of policy forms and rate filings
- Credentialing procedures (other than those affected by specific pre-emption on provider participation)
- Agent Licensing
- Filing and review of provider contracts
- Enforcement of loss-ratio standards
- Standards and enforcement of commission limitations

FINANCIAL REPORTING BY STATE LICENSED M+C ORGANIZATIONS

The regulation of a state licensed M+C organization's solvency is primarily a state responsibility. However, Federal regulations at 42 CFR 422.502, 516 and 552 require each M+C organization to report to HCFA, in the manner that HCFA requires, information demonstrating that the organization has a fiscally sound operation. Therefore, even though state regulators have the primary responsibility for solvency regulation, HCFA does have the responsibility of ensuring that it contracts only with fiscally-sound organizations.

Given these new roles and responsibilities, the NAIC and HCFA have committed to and individual states are encouraged to commit to open and regular communication and the mutual exchange of information about M+C organizations. The NAIC will explore, and if practical, will work with HCFA to establish means to share the following:

- On-line access to the NAIC's data base of financial information of licensed insurers engaged in Medicare+Choice business.
- Findings from state financial examinations.
- Findings from state market conduct reviews.
- Findings from any other state reviews of M+C organizations.
- Updated phone lists and organizational charts of state insurance departments with reference to key staff responsible for solvency regulation and reviews along with policy form and rate reviews.
- Current information about state solvency requirements for M+C organizations.
- Listing of state insurance department web sites, including the location of solvency related information.

While the states have the primary responsibility to regulate M+C organizations, HCFA in its role as contractor will also monitor the financial solvency of M+C organizations. HCFA will require them to report the following information:

- Annual and quarterly financial statements as designated by the NAIC consisting of the NAIC Life and Health, Property and Casualty, or HMO Blank.
- Annual certified audit, by a qualified independent accountant.
- Information as pertaining to the disclosure of ownership and control of the M+C organization.

HCFA will explore, and if practical, will work with NAIC and state insurance departments to establish means to share information developed from the above processes and from audits conducted by HCFA.

In addition, all M+C organizations must adopt and maintain arrangements satisfactory to HCFA to:

- Protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the M+C organization; and
- Provide for the continuation of enrollee health care benefits in the event of insolvency for the duration
 of the contract period for which payment has been made and for enrollees that are hospitalized through
 discharge.

Confidentiality Guidelines:

HCFA and the state insurance departments will, to the extent they can under the Federal Privacy Act, the Federal Freedom of Information Act, state open record laws and similar laws, keep information shared between them confidential if so requested.

REGULATION OF FEDERALLY WAIVED PSOS

BACKGROUND

While an M+C organization must generally be licensed under state law, or otherwise authorized to operate under state law, as a risk-bearing entity eligible to offer health insurance or health benefits coverage, a PSO can obtain a Federal waiver from this requirement if it is denied state licensure for certain reasons. (The Federal definition of a PSO and the conditions for a waiver are summarized below). By superseding any provisions of state law relating to the licensing of an organization that conducts the M+C business, the waiver allows a PSO to offer an M+C plan or plans without state authorization. The waiver is only effective for the particular state for which it is granted and is limited to a 36-month non-renewable period.

Nothing in Federal law or HCFA's regulations relating to M+C would specifically require a state to change its scheme of regulation of risk-bearing entities to accommodate PSOs that only offer services to Medicare beneficiaries. Also, states are not required to set up a separate license specifically for PSOs. Each state is permitted to determine whether a PSO should be licensed as an HMO, PSO, PPO or other type of risk-bearing entity.

Under Federal law to obtain a waiver, a PSO must:

- Be established or organized and operated by providers.
- Provide a substantial portion of services (i.e. 70 percent for PSOs in urban areas and 60 percent for PSOs in rural areas) directly or through its affiliated providers.
- Be effectively controlled by providers as evidenced in the case of a for profit organization, for example, by the providers having a majority financial interest.
- Allocate substantial financial risk to each of the affiliated providers, if the entity is an affiliated provider model PSO.

Waivers may be granted by HCFA in cases where:

- A waiver request is made before November 1, 2002; and
- A state does not approve nor deny an application within 90 days of receiving a substantially complete application; or
- A state denies an application for reasons not related to solvency and the requirements upon which the denial is based are not generally applicable to other substantially similar businesses (i.e., the application is treated in a discriminatory fashion); or
- The state denies an application on the grounds that the PSO does not meet a state licensure requirement to offer any other product or plan other than the Medicare+Choice plan; or
- The state denies an application for reasons related to solvency and the state's solvency requirements, procedures or standards are different than the Federal PSO solvency requirements; or
- The state imposes information or documentation requirements for solvency that are different than those established by HCFA; or
- The state has notified the organization in writing that it will not accept the application.

A waiver only enables a PSO to operate a M+C contract; a waiver does not enable a PSO to offer commercial or other lines of risk-bearing business in a state. Waivers will not be available to entities that do not qualify as a PSO under Federal law.

GUIDELINES FOR THE WAIVER REQUEST AND APPROVAL PROCESS

Although FWPSOs are not subject to state licensure authority, state regulators will play a significant role in HCFA's waiver process because PSOs only become waiver-eligible after they attempt to become state licensed. This section contains a listing of HCFA's responsibilities and state participation during this waiver request and approval process as well as guidelines HCFA intends on using for determining whether a PSO submitted a "substantially complete" state application.

HCFA Responsibilities

- Notify the appropriate state regulatory agencies of any organization requesting a waiver in their state.
- Verify any waiver requesting organization's waiver eligibility by obtaining the state's account of the
 organization's attempt to become state licensed and the specific circumstances upon which the waiver
 request is based.
- Notify the state in writing of any organization that has been granted a waiver of the M+C state licensure requirement.
- Notify the state when a FWPSO will begin operating under the M+C contract.

- Obtain a summary of the waiver requesting organization's proposed business plan and either a summary
 of its state application package or documentation that the state has notified the applicant in writing that
 its application for licensure has been rejected. This information will be submitted to the state for
 confirmation.
- Confirm with the state that there is not a material difference between the legal entity requesting the waiver and the legal entity that applied for a state license.

Suggested State Actions

- Act in good faith to either approve or deny license applications in a timely manner.
- Provide applicants with accurate guidance and adequate assistance before and during the application process.
- Respond to HCFA's request for information regarding the state's licensing process, requirements that are applicable to risk-bearing entities and the waiver requesting organization's attempt to become state licensed.

Substantially Complete Application

For the purposes of determining an organization's eligibility for a waiver if the state does not approve or deny an application within 90 days of the application being "substantially complete", HCFA will consider an application to be substantially complete under the following circumstances:

- The state gives notice to the organization that the application is complete.
- The state has not notified the organization, in writing, as to the completeness of its application within 60 days of the date of submission of an application. In this case, HCFA will consider the date the state received the initial application to be the date the state received a substantially complete application.
- An organization may demonstrate to HCFA that it has submitted all of the information requested by the state after the state has notified the organization that its application is incomplete, or the state has failed to notify the organization within 30 days from the date it received additional information that the information is still incomplete. If HCFA agrees that the application is complete, it will be considered complete when the state received the additional information.
- HCFA will make a final determination in a dispute over the date the state received a substantially complete application only after and based on consultation with the state and the organization.

While each state typically has requirements as to what constitutes a complete application, the following list illustrates elements that states typically may require in an application that will be accepted by HCFA as part of a substantially complete application:

- An executed application form.
- A business plan to include a description of the PSO operations, source of funding, and method of funding; identity of all ownership interests; description of the PSO health care plan, facilities and personnel, service area, claims handling procedures and estimated claims processing time. The plan must also include an organizational chart indicating the names, addresses, percentage of the PSO ownership by stockholders, holding company, ultimate parent, affiliates, and subsidiaries.
- A copy of the basic organizational documents, such as the articles of incorporation, articles of
 association, partnership agreement, trust agreement or other applicable documents, certified by the
 applicable domiciliary official.
- A copy of the articles, bylaws, rules, and regulations or similar document(s) regulating the conduct of the internal affairs of the PSO.

- A list of the names, addresses and official positions of the persons who are to be responsible for the conduct of the affairs of the applicant, including all members of the board of directors, board of trustees, executive committee, or other governing board or committee, or the principal officers in the case of a partnership or association, along with a biographical affidavit for each.
- Copies of any contracts made or to be made between the applicant and any providers and sub-providers.
- A description of the product(s) to be offered and method of marketing including, at a minimum, proposed advertisements, solicitation material, use of brokers and agents, use of PSO staff and marketing research that will indicate the ability to meet the enrollment projections.
- Financial statements in the NAIC standard HMO format showing the PSO's assets, liabilities and net worth.
- A copy of the most recent regular, certified financial statement audited by an independent Certified Public Accountant.
- Financial projections on a statutory accounting basis that include a three-year projection of the initial operating results anticipated, and a statement as to the sources of working capital, as well as any other sources of funding. Such filing usually includes pro forma balance sheets and income statements conforming to the format of the HMO convention blank as adopted by the NAIC. The projections also contain projected member-per-month enrollment, by state, at a calendar year end, and a concise summary
- A description of the reinsurance, stop loss, medical malpractice, insolvency, general liability, fidelity of
 all assumptions used to generate the projections or any other insurance coverage being considered as
 protection for the applicant or its enrollees.
- A copy of any management, administration or cost-sharing agreements.
- Actuarial opinion supporting the proposed premiums or rates to be charged and the underlying actuarial
 report reflecting the methodology and assumptions used in arriving at the rates used within the
 projections. The opinion and report must be prepared using generally accepted actuarial standards and
 principles.
- Acceptable securities for statutory deposit, including copies of any custodial arrangements.
- A listing of contracting providers by specific geographic area and by specialty within each geographic area, along with a map clearly indicating the desired service area.
- A description of the procedures and programs to be implemented to meet the quality of health care and provider network adequacy requirements.
- A copy of the quality assurance program, grievance procedures and evidence of coverage to be issued to the subscriber.

FWPSO FINANCIAL REPORTING

In lieu of state solvency requirements, FWPSOs must meet the Federal PSO solvency requirements at 42 CFR 422.380. These requirements were developed by a Negotiated Rulemaking Committee consisting of insurance industry representatives, health care providers, beneficiary advocates, state regulators, and HCFA representatives. Regulation of FWPSO solvency is solely HCFA's responsibility.

Section 1857(d) of the Social Security Act also requires each M+C organization, including FWPSOs, to report such financial information as the Secretary may require demonstrating that the organization has a fiscally sound operation. By regulation, an M+C organization must have an effective procedure to develop, compile, evaluate, and report to HCFA, its enrollees, and to the general public, at the times and in the manner that HCFA requires, while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information with respect to: (1) the cost of operations; (2) information demonstrating that the M+C organization has a fiscally sound operation; and (3) other matters that HCFA may require (42 CFR 422.516).

Specifically, FWPSOs will be required to file annual and quarterly financial statements using the NAIC format for HMOs, Life and Health insurers, or Property and Casualty insurers and annual certified audits with HCFA. Any annual or quarterly financial statements or audits submitted to HCFA could simultaneously be made available to the Insurance Department (or primary regulator of solvency) in the state(s) where the PSO operates, to beneficiaries and to the general public.

HCFA will also collaborate with the state(s) to facilitate the regulation of FWPSOs through open and regular communication and mutual exchanges of information about FWPSOs fiscal soundness. For example, HCFA will communicate, at the state's request, any adverse findings to state regulators and provide them with a copy of any plan submitted to HCFA by an FWPSO to meet the initial and ongoing solvency standards, or to restore an impairment of such solvency standards. Finally, HCFA will develop a financial transition plan for when FWPSOs must come back to state regulation. HCFA encourages states to work with it in the development and implementation of the plan. Because FWPSOs are solely under Federal regulation during the three-year waiver period, any FWPSO information sent to the state insurance department (or primary regulator of solvency) is for informational purposes only and states should direct public requests for this information to HCFA. HCFA and the state insurance departments will, to the extent they can under the Federal Privacy Act, the Federal Freedom of Information Act, state open record laws and similar laws, keep information shared between them confidential if so requested.

FWPSO COMPLIANCE WITH STATE CONSUMER PROTECTION AND QUALITY STANDARDS

Background

Although the waiver supersedes any state requirements related to licensure, including state solvency standards, the waiver is conditioned upon the PSO's compliance with applicable state consumer protection and quality standards. The continuation of the waiver for each subsequent year of the three-year eligibility period is conditioned upon the PSO's continued compliance with applicable state consumer protection and quality standards. This requirement is incorporated into the contract between HCFA and all FWPSOs.

Enforcement

There are three options for ensuring ongoing compliance of M+C organizations and their M+C plans, with applicable consumer protection and quality standards.

First, HCFA and a state may enter into an agreement whereby the state agrees to monitor and enforce the consumer protection and quality activities that would apply in the state to the organization if: (1) the organization were licensed under state law; (2) the activities were generally applicable to other M+C organizations and plans in the state; and (3) such activities were consistent with M+C standards not otherwise

preempted. This agreement would specify mechanisms by which compliance activities are undertaken by a state and may not otherwise lengthen the time required to review and process applications for the aforementioned waivers.

Second, if a state does not enter into an agreement with HCFA to monitor and enforce the consumer protection and quality activities, HCFA will be required to enforce the individual state's consumer protection and quality standards. This can be accomplished in one of two ways. First, HCFA may monitor and enforce a given state's consumer protection and quality standards to the extent such requirements exceed federal standards in these areas and are not otherwise superseded by Federal law that applies to state-licensed entities. For this to occur, the state would need to provide HCFA with specific information regarding applicable state standards and procedures and the related monitoring and enforcement activities necessary for ensuring compliance with them. To the extent possible, the state would be asked to provide HCFA with a description suitable for inclusion in the market material and evidence of coverage, or other member contract document of PSOs enrolling residents of the state. HCFA will not be bound by such procedures but will use them as the basis for determining a compliance and enforcement mechanism that is compatible with HCFA procedures for determining compliance and enforcing other M+C standards. It might also be necessary for HCFA to ask state personnel to provide HCFA staff with any requisite training necessary for ensuring appropriate levels of compliance.

Finally, in instances where a state determines that the consumer protection and quality assurance standards articulated in HCFA's Quality Improvement System for Managed Care (QISMC) program are equal to or greater than what would otherwise be applicable to other M+C organizations, HCFA could enforce QISMC standards to meet this requirement. That is, HCFA would utilize its QISMC standards in lieu of a state entering into an agreement with HCFA to enforce its own standards, or in lieu of HCFA directly monitoring and enforcing applicable state consumer protection and quality standards. HCFA may impose, monitor and enforce its own quality standards (known as QISMC) in place of state standards, if QISMC standards are equal to or greater than state standards and if the state agrees to such substitution.

Regardless of which method is chosen to ensure that FWPSOs comply with applicable state consumer protection and quality assurance standards, states will be asked to formally indicate their choice to HCFA. In instances where a state chooses to enforce its own standards, the state and HCFA will enter into a formal agreement specifying mechanisms by which compliance activities are undertaken. Such an agreement may not lengthen the time required by HCFA to review and process applications from PSO applicant organizations for federal waivers.

(ATTACHMENT A)

HCFA CONTACTS FOR M+C GUIDELINES

State Licensed M+C Organizations

M+C State Licensure Requirement Carlos Zarabozo Rebecca Cardozo	202/690-7577 410/786-0300	czarabozo@hcfa.gov rcardozo@hcfa.gov
2. Federal Preemption		
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Waiver Request and Approval Proces	c c	
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2. Financial Reporting		
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Marty Abeln	410/786-1033	mabeln@hcfa.gov

(ATTACHMENT B) MEDICARE + CHOICE (M+C) STATE CERTIFICATION REQUEST

1. M+C Applicant Information:(Organization t				
Name_				
AddressCity/State/Zip				
7 1				
2. Type of State license or Certificate of Authorlicenses)	ority currently held:(Check more than one if multiple			
☐ HMO ☐ PSO ☐ PPO ☐ Inde Comments:	emnity POS Other			
3. Type of (M+C) application with Health Car (Check all that are appropriate)	re Financing Administration (HCFA):			
☐ HMO ☐ PPO ☐ MSA ☐ Network MSA ☐ With POS ☐	\mathcal{E}			
4. Geographic areas that licensed entity is auth	orized to serve for non -M+C products:			
5. Geographic areas that licensed entity is auth	orized to serve for M+C products:			
(Below the Line, Complete by the Appropriate	e State Official)			
6. State official reviewing M+C State Certifica	ation Request:			
Addraga				
City/State				
Telephone				
7. Name of other State agencies whose approv	val is required for licensure:			
Agency Contact Person				
Telephone				
1 Cicpitolic				

8. Please describe any incremental review, be conduct to specifically authorize this organizat product approval, assessment of network ade	tion to enter th	
9. Scope of State licensure. M+C Applican organization is within the scope of its State lic determine that risk bearing entities licensed to may not offer an M+C plan without obtaining	censure/authorion offer less that	zation. (For example, a State may n comprehensive services (e.g., dental plans)
☐ is within the scope of Applicant's State licensure	€	☐ is not within the specific authority granted by the State to operate as a M+C organization. (Fully explain)
10. a. Is the organization commercially licens requirements? If the organization is not commedoes the organization meet a level of financial organization.	nercially licens	sed, to the best of the State's understanding,
Commercially licensed: Yes ☐ No ☐]	
Meets level of financial solvency:	☐ Yes	□ No
	-	has the responsibility for assessing whether sufficient to operate as an M+C organization.
Stat	te Certificati	i <u>on</u>
I hereby certify to the Health Care Financing Adoing business as and that the aforemention the type of Medicare + Choice contract(s) income) is licens ned organizat	sed as a risk bearing entity in the State of ion is authorized to bear risk associated with
		Agency
Date		Signature
		Title

Certification Form - Revised 12/98

INSTRUCTIONS

(M+C State Certification Form)

General:

This form will be included in all Medicare + Choice (M+C) applications. The Applicant is expected to complete the items above the line (items 1 - 5) and the appropriate State Agency Official will complete those items below the line (items 6 -8). The Applicant will complete their part first and forward the form to the appropriate State Agency Official where it will be completed and returned to the Applicant. The form should be included in the application for a M+C contract when it is submitted to the Health Care Financing Administration (HCFA) for review. It should be placed in the Organization And Contractual section under the Legal Entity subsection.

The questions should be fully completed. Sufficient space has been provided, however, if additional space is needed, please add pages to provide a more complete response. Provide additional information whenever you believe further explanation will clarify the question.

The M+C State Certification Form demonstrates that the contract being sought by the Applicant from HCFA is within the scope of the license granted by the appropriate State regulatory agency and is authorized to bear risk.

Items 1 - 5 (to be completed by the Applicant):

- 1. List the organization that will enter into the M+C contract with HCFA.
- 2. The Applicant should list the type of license currently being held in the State where an M+C contract is be sought.
- 3. Applicants must specify the type of M+C contract being requested from HCFA. HCFA wants to be certain that the license held by the State is a health care license and most directly resembles the type of contract being requested by HCFA.
- 4. List the counties that the Applicant is licensed to provide health care to non Medicare beneficiaries.
- 5. List the counties that the Applicant is requesting to provide health care services under the M+C contract.

<u>Items 4 - 8 (to be completed by State Official):</u>

- 6. List the reviewer's pertinent information in case HCFA needs to communicate with the analyst actually doing the review at the State level.
- 7. Some States require several departments/agencies to review licensure requests. HCFA wants to know which agencies require such approval.
- 8. HCFA is trying to determine for each Applicant and for each State the type of incremental review that is performed before a licensed organization can enter the M+C line of business. Will your review encompass a thorough review of the hospital, physician and other ancillary services in the area? Will there be an understanding that additional medical personnel will be required to provide a M+C contract? Do you check into the product being requested and compare it to the existing organization to see if it can carry out the contract? Is there any ongoing review of the Applicant and is the Applicant required to inform you of any changes in the product or delivery system if they occur?
- 9. It is imperative that the M+C contract be within the scope of the State license. If holding an indemnity license is inconsistent with the ability of the Applicant to provide comprehensive health care services under a M+C contract of the type requested, provide a complete explanation.

10. Check the box which indicates whether the Applicant has a commercial license and whether it meets the financial solvency requirements to operate under a M+C contract.

(ATTACHMENT C) Organization Determinations, Appeals & Grievances Under the Medicare+Choice Program

Medicare beneficiaries enrolled in any Medicare+Choice (M+C) organization have a right to request timely organization determinations and to appeal decisions concerning their Medicare benefits. Additionally, M+C enrollees have a right to file grievances regarding any other concerns or problems with their M+C organization. Beneficiaries have these rights regardless of the type of M+C organization in which they are enrolled -- including state-licensed or federally-waivered provider-sponsored organizations (PSOs).

An appeal includes any of the procedures that deal with the review of an adverse organization determination. An adverse organization determination is the M+C organization's initial denial of payment or service -- this decision is unfavorable to the enrollee in whole or in part. Only complaints concerning organization determinations are subject to the M+C appeal process. Appeal procedures include reconsiderations by the M+C organization, and if necessary, an independent review entity, hearings before Administrative Law Judges (ALJs), review by the Departmental Appeals Board (DAB), and judicial review. All other complaints are subject to the M+C organization's grievance requirements.

A grievance is any complaint or dispute other than one involving an organization determination. For example, an enrollee might file a grievance if he or she received a service but believed that the demeanor of the person providing the service was insulting or otherwise inappropriate. Also, grievance procedures would apply when an enrollee disagrees with an M+C organization's decision not to provide an expedited determination. Each M+C organization is required to provide meaningful procedures for hearing and resolving grievances in a timely manner.

Subpart M of Part 422, 42 C.F.R., sets forth requirements for M+C organizations related to organization determinations, appeals and grievances. Under the standard process, an M+C organization is required to make a decision with respect to an enrollee's initial request for service (organization determination) as quickly as the enrollee's health requires. M+C organizations must make organization determinations according to an enrollee's health needs, and in no case later than 14 calendar days after the organization receives the request. In the case of an enrollee's initial request for payment, an M+C organization must meet requirements set forth at 42 C.F.R. § 422.520. That is, an M+C organization must make 95% of its determinations regarding "clean claims" (e.g., claims without any defect or impropriety) within 30 calendar days. All other claims must be paid within 60 calendar days.

An enrollee may file a standard appeal (or reconsideration) if his or her M+C organization denies a service, or terminates or refuses to pay for services that he or she believes should be covered. If the enrollee's appeal concerns his or her request for a service, the M+C organization must render a decision as quickly as the enrollee's health requires and in no case later than 30 calendar days. If the enrollee's appeal concerns a request for payment, then the M+C organization has 60 calendar days to

render its decision.

An enrollee may be eligible for either an expedited organization determination or an expedited reconsideration (within 72 hours) if waiting for a standard decision could seriously jeopardize his or her life, health or ability to regain maximum function. If a physician makes or supports an enrollee's request for expedited review -- regardless of whether the physician contracts with the M+C organization -- and the request indicates that the standard timeframe could jeopardize the enrollee's health, the M+C organization must review the case within 72 hours.

In both the case of expedited and standard organization determinations and reconsiderations, an M+C organization may permit an extension of up to 14 calendar days. An extension is permitted if the enrollee requests the extension or if the organization justifies a need for additional information and shows how the delay is in the interest of the enrollee. For example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's initial decision to deny coverage and, therefore, justify the use of an extension.

If, upon reconsideration, the M+C organization does not decide in the enrollee's favor, the M+C organization automatically forwards the enrollee's case to an independent review entity that contracts with Medicare (currently, the Center for Health Dispute Resolution). If Medicare's contractor denies any part of the enrollee's request, then the contractor advises the enrollee of his or her right to appeal to an ALJ of the Social Security Administration. If an enrollee meets the requirements (there must be \$100 in controversy), then the enrollee has 60 days to file an appeal with an ALJ. Although the M+C organization does not have a right to request an ALJ hearing, the M+C organization must be made a party to the ALJ hearing. If the ALJ agrees that the enrollee cannot receive the service or payment, then the enrollee has 60 days to file for review by the DAB. At the DAB level, there is no required amount in controversy. Once the enrollee is at the DAB level, if the beneficiary is not completely satisfied with the outcome of the administrative appeal process, then he or she may file suit in federal court within 60 days. To reach the judicial review level, there must be at least \$1,000 in controversy. (Note: the M+C organization may file for review at the DAB and judicial review levels.)

Furthermore, if an enrollee believes he or she is being discharged too soon from a hospital, the enrollee has a right to immediate review by the Peer Review Organization (PRO) in his or her state. During immediate PRO review, the enrollee may be able to stay in the hospital at no charge and the hospital cannot discharge the enrollee before the PRO reaches a decision.

In addition to reducing the timeframes within which organizations must render standard service-related determinations, the M+C regulation made several other significant improvements to the beneficiary appeal process. For example, optional supplemental benefits are now subject to appeal. Additionally, denials based on a lack of medical necessity must be reconsidered by a physician who has expertise in the field of medicine appropriate to the services in question and who did not participate in the initial organization determination. M+C organizations are also restricted from taking any punitive action against a physician who requests or supports an enrollee's request for expedited review. Further, M+C organizations are

required to authorize or provide services as quickly as the enrollee's health requires, but no later than 30 days when the plan reverses its adverse determination in full or no later than 60 days from the date of a decision by the independent review entity or higher level of review. An M+C organization must pay for a service within 60 days.